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Is the pharmaceutical industry overpowering the medical profession?

DISCUSSION

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ABSTRACT

Doctors' reported loss of autonomy in the current policy climate and the subsequent deprofessionalisation of medicine can be attributed to many factors. The pharmaceutical industry accounts for a large proportion of healthcare costs, with the professional relationship between the industry and medical profession raising ethical concerns. Developing potentially life-saving products and potentiating scientific advances are some of the many good attributes of the pharmaceutical industry. The dependence of medical care on the production of pharmaceuticals is undeniable. However, it could be argued that the pharmaceutical industry takes advantage of this relationship, fuelled by financial motive. Conversely, there could be a complex interplay of factors driving a power imbalance in the pharma/clinical relationship. By reviewing literature in the field, this viewpoint article explores these multifaceted factors.

Medical students are to enter a profession at the forefront of improving the health of individuals and populations. Scientific innovation, particularly in the field of the pharmaceutical industry, is one of the exciting ways through which physicians are able to practise medicine through prescribing. However, with an increasing array of drugs available, it is important for newly qualified doctors to be able to navigate their way through pharmaceutical industry marketing to ensure optimal clinical practice. (1)

In the past, healthcare was dominated by a paternalistic approach, with people having little access to the medical knowledge held by doctors. (2) The advent of technology and a shift in attitude has resulted in a more informed public, who expect to be involved in decisions affecting their care. (3) For doctors, this means patients are possibly more accountable for their own health, but potentially less trusting of the medical profession. (3) (Haug, 1973) predicted professionals will lose *"their monopoly over knowledge, public belief in their service ethos and expectations of work autonomy and authority over the client"*. (4)

Barriers that prevent the profession from carrying out its moral duty to improve the health of general society could reduce professional autonomy. The industry may encourage reliance on prescribed medication, thereby changing the way society responds to health problems and creating a market for products beyond health needs. (5) This article will explore the extent of the influence of the pharmaceutical industry on the medical profession. The Government and governing bodies have an impact on drug availability, as well as prescribing practitioners. Market forces, patient demand and drug development costs may justify its presence and influence in society.

The Government

It could be argued that governmental policy encourages pharmaceutical influence over the medical profession. Foucault states *"the first task of the doctor is political: the struggle against disease must begin with a war against bad government"*. The Government negotiates with the pharmaceutical industry to decide the availability of patented or generic drugs for prescription, as well as enforcing caps and budget restrictions on the profession. (6) Most recently, The National Institute for Health and Care Excellence (NICE) has set a cap on drugs costing more than 20 million pounds a year, which is a breach of a pledge made in the Conservative Party's manifesto. (7) The Government also introduced General Practice budgets in 1991 as an attempt to contain growth in NHS expenditure on prescribed drugs. (8) Therefore, the Government may actually be a driver of the pharmaceutical industry's profits in the UK.

Conversely, 2009 Patient Access Schemes have been introduced, offering price reductions on drugs which were unlikely to meet NICE's cost-effectiveness criteria. (9) Therefore, the presence of governmental policy and evidence-based medicine could contain the industry, protecting the professional power of the medical doctor.

NHS and NICE

NICE is an important source of guidance for the use of health technologies within

the NHS and considers both the medical and economical indications. Therefore, NICE ultimately determines the influence of the pharmaceutical industry. The NHS Constitution states patients have the "*right to drugs and treatments recommended by NICE if their doctor believes they are clinically appropriate*". The NHS is therefore legally obliged to fund and resource medicines recommended by a NICE technology appraisal within three months of the published appraisal. (10,11) This legal obligation empowers the pharmaceutical industry to create drugs, which they know will have to be provided (if clinically appropriate). It may also give patients a sense of entitlement to medication that may not be commonly prescribed, for instance by lacking an evidence-base for its efficacy. Patients may feel they can challenge or pressurise their doctor into prescribing medications due to the presence of the publicly funded NHS through general taxation.

Conversely, NICE may be enabling the pharmaceutical industry. The World Health Organisation (WHO) Report was critical of the pharmaceutical industry's influence on NICE, particularly expressing that manufacturers should not be members of the drug appraisal committee. (12) By allowing manufacturers into this committee, NICE could be influenced to approve drugs endorsed by those manufacturers. This may undermine the regulatory system in place for NHS prescribing and potentially take advantage of NICE's position in developing public health guidance, with guidelines being shaped by the financial interests of pharmaceutical industry shareholders.

The role of NICE could be challenged with the impending exit of the United Kingdom from the European Union. Currently, NICE is a lead partner in the European Network for Health Technology Assessment and therefore has a global influence. Although there is much uncertainty regarding the details of this at present, there will be relocation of the European Medicines Agency away from London. This will affect the evidence base for Health Technology Assessments due to less access to European research funding, as well as possibly increasing the cost of medicines and healthcare due to the expense of doing business as a small country. (13)

It can be seen that the availability of possibly life-saving medication has become increasingly dependent on economic factors, especially in a resource-poor public-sector climate. It is considered a doctor's decision to recommend treatment if deemed appropriate, but there are several notable cases where such clinical decisions have been undermined or delayed. Notably, NICE rejected trastuzumab emtansine (Herceptin) for use in the NHS for advanced breast cancer in 2015 for the sole reason of it being too expensive. The drug was reinstated after a deal was made with the manufacturer Roche. (14) The drug lumacaftor-ivacaftor (Orkambi) for cystic fibrosis has also been denied for reasons of cost-effectiveness, despite doctors predicting possible benefits for over 3000 patients, with reductions in hospital admissions and antibiotic use. (15, 16)

Prescribing patterns

It may be the medical profession itself encouraging the pharmaceutical industry.

Medication costs the NHS over 7 billion pounds a year. (17) According to NHS Digital “*In 2016 there were 1,104.1 million items dispensed, which is an increase of 1.9 per cent (20.5 million) on the number dispensed in 2015*”. (18) In Britain, increased prescribing powers have been granted to nurses as they are allowed to prescribe independently in the community, within their area of competence or as part of an agreed plan by a doctor. (19) This could result in a greater number of drugs being issued to patients.

Liberal prescribing patterns encourage the pharmaceutical industry, creating demand and financial motive to produce more medication. In doing so, the NHS is promoting an ideology that drugs can solve health problems as opposed to targeting the cause of a disease through prevention strategies. Although general health in society has improved over time, this has not been largely accounted for by the greater use of medicines, therefore proving the theory that drugs do not cure disease. (20)

Evidence-based medicine

The use of scientific research in clinical practice through evidence-based medicine is well-established in healthcare through clinical guidelines. This uses scientific evaluation of research literature to guide clinicians on how to practise medicine. (21) There is a correlation between medical advances and professional decline. This is due to the automation of medical procedures, such as using sound waves instead of scalpels to treat kidney stones, which threatens physicians as ‘operators’ as opposed to masters of their technology. (22)

The presence of evidence-based guidelines could deprofessionalise medicine by taking away a clinician’s choice and pressurising them to practise medicine in a particular way. This could work in the favour of pharmaceutical companies, especially when using evidence in clinical trials.

The pharmaceutical industry is in a unique position as it can use scientific evidence to serve its own interests, especially in the pre-approval stage of drug development. Initial drug testing is carried out by laboratory scientists or pharmacologists, employed by pharmaceutical companies themselves. This means they could selectively use the information found when seeking approval for new drugs. (23) It is therefore important for professionals to carefully consider information supplied by drug companies and the media.

Pharmaceutical companies can also influence doctors to prescribe specific drugs based on incentives, such as free samples. This could lead to a loss of trust and autonomy in the profession. The industry is able to educate and advise on the latest drugs, although this information is unregulated. Educating prescribers is important, however ensuring this information is accurate and balanced will allow professionals to make well-informed decisions. (24)

Market forces

There is a rise of corporatisation within healthcare, with greater access to private healthcare in the UK than ever before. (6) This could create a societal divide in terms of those who receive medication, encouraging a feeling of entitlement to medication regardless of what the doctor thinks.

It was recognised that biologic drug spending was rising; biosimilars were therefore reverse-engineered to reduce costs. (25) It may be that high drug cost is temporary and will be driven down to become more affordable for the NHS. Market changes are expected and may be a challenge to the medical profession that it will have to adapt and adjust to accordingly.

An economic evaluation of biologics suggests acceptable cost-effectiveness in the long-term due to stabilising disease to reduce costly inpatient surgery care, which accounts for *"44% of the lifetime costs for a typical patient"* with Crohn's disease. (26) This justifies the expense of these drugs, while also proving a positive effect to society.

Some medication patented in the developed world is copied in developing countries, where patent rights of pharmaceutical products are not protected. (27) Therefore, manufacturers who have spent money on developing these products are outcompeted when it comes to selling them. This is troublesome to manufacturers' profits, although perhaps enables the medical profession as drugs can be provided at a fairer price to society.

Research and development

Drug research and development (R&D) is often expensive and timely, which means companies often have to charge high prices to the medical profession to cover their costs. The pharmaceutical industry may use this financial motive to influence the prescription of certain medications.

It can take 10-15 years for drug approval after multiple phases of trials. Data conducted by pharmaceutical manufacturers is extrapolated from these trials and applied to the population, although the majority of trials are conducted on healthy, young sample groups. Doses in trials are often high as manufacturers need to prove their drug is effective, as opposed to finding the lowest possible therapeutic dose. (23) It may be tempting to omit or manipulate data that could negatively affect trial results; this may not become apparent until after drug approval, adversely affecting patients.

An example concerns the risk of suicidality in adolescents taking selective serotonin reuptake inhibitor (SSRI) antidepressants, such as fluoxetine and paroxetine, coming to light years after drug approval. Aggressive behaviour, restlessness and increased hostility

in children and adolescents were described, with some reports showing cases of violence and murder. (28) For paroxetine in particular, drug companies retrospectively noted that for adults of all ages with depression, the frequency of suicidal behaviour was higher in patients (0.32%) compared to those treated with placebo (0.05%). (29)

There was a noticeable discrepancy between published and unpublished trials, which was shown in a 2004 UK review using Medicine and Healthcare products Regulatory Agency data. Under-reporting of this side effect was found to be due to limitation in the design of clinical trials, such as response-based selection bias and insufficient lead-in periods. (28) Therefore, it is important to be wary of published trial information, with clinical study reports being far more reliable in determining the risk of serious harm in prescribed medications.

R&D costs are estimated by industry-funded studies at £1.15 billion per drug. (30) It is difficult to ascertain whether drug prices are justified or whether they are a result of pharmaceutical greed. Scannell et al. (31) attributes the high production cost to a decline in R&D efficiency, possibly due to overcautious regulation of the industry. It was noted that trials often fail early due to the absence of a drug's positive effect in trials of low patient numbers, therefore increasing costs in the long term. Pharmaceutical financial motive may therefore negatively influence the medical profession.

The future

The medical profession relies on the pharmaceutical industry; instead of fighting against commercialism, working together may be a solution to the issues faced. This could be carried out through transparency in research and clinical endeavours. It may be more applicable to influence demand for pharmaceuticals via prescribing doctors. (32) The industry could work with hospital consultants and GPs to identify medication demand. Patients do not have the power to obtain drugs themselves without a prescription. Giving control back to the doctor through identifying prescribing needs in their experience and feeding this back to drug companies could be a solution. This will empower the profession, while still ensuring manufacturers have products to sell, as medication does of course play a key role in healthcare provision.

Further regulation of the pharmaceutical industry globally would improve efficiency and availability of life-changing medication to all populations. Improving productivity would drive down cost prices and enable the future viability of the healthcare system. (31) More realistic government funding to the pharmaceutical industry to match the increase in production costs for pharmaceuticals would relieve financial pressures on manufacturers. Furthermore, independently funded and transparent research could be carried out to ensure patient safety. (23)

Conclusion

As a student entering the profession, it is important to be aware of the changing

nature of what it means to be a medical professional in society. This ultimately means acknowledging that the profession is dynamic, influenced by market forces and governed in a way that influences clinical practice. Considering public perception of medication, as well as their view of professionals, is imperative in making decisions on clinical practice. The pharmaceutical industry does have the power to influence the medical profession, however doctors still have overriding responsibility and a duty of care on medication prescribed to their patients.

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